



MAIL STOP APPEAL

BRIEF - PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	R. Crowley	Attorney Docket No.	BSME124883
Application No:	09/879,433	Art Unit:	3735 / Confirmation No.: 4101
Filed:	June 12, 2001	Examiner:	D.M. Shay
Title:	MUCOSAL ABLATION		

SUBSTITUTE APPEAL BRIEF

Seattle, Washington
January 10, 2007

TO THE COMMISSIONER FOR PATENTS:

This Substitute Appeal Brief is being filed in response to the Notice of Non-Compliant Brief mailed August 25, 2006. In the Notice, it was indicated that the Supplemental Appeal Brief filed September 20, 2004 in support of Appellant's request for Reinstatement of the Appeal under 37 C.F.R. 1.193(b)(2) was defective for failing to comply with the requirements of 37 C.F.R. 41.37(c) as set forth in the communication sent by the Board of Appeals on May 5, 2006.

Appellant wishes to thank Examiner Shay for the interview conducted on August 8, 2006. In the interview, the form of the Substitute Appeal Brief was discussed as well as how to respond to the request of the Board of Appeals and Interferences (hereinafter "the Board") regarding the status of Claim 26. No agreement was reached.

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I. REAL PARTY IN INTEREST

The real party in interest in the above-identified patent application is Boston Scientific Corporation, Natick, Massachusetts. An Assignment perfecting Boston Scientific Corporation's interest in this application was recorded by the U.S. Patent and Trademark Office on January 21, 2003, at Reel/Frame 013675/0947.

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II. RELATED APPEALS AND INTERFERENCES

Appellant does not have any knowledge of related appeals, interferences, or judicial proceedings that may directly affect or be directly affected by or have a bearing on the decision of the Board in the pending appeal.

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III. STATUS OF CLAIMS

The application on appeal was initially filed with Claims 14-33 presented through a Preliminary Amendment filed with the application. Claims 1-13 were canceled by the Preliminary Amendment without prejudice. Claims 34-39 were added through a second Preliminary Amendment dated February 8, 2002. Claims 14-39 were rejected in a first Office Action issued by the United States Patent and Trademark Office on October 15, 2002. In response to the first Office Action, Claim 40 was added through an Amendment dated January 13, 2003.

Claims 14-40 were generally rejected to in the Office Action Summary of a final Office Action dated April 17, 2003 (hereinafter referred to as the "the final Office Action"). Claims 14-25 and 27-40 were substantively rejected in the final Office Action on pages 2-5 as follows:

- 1) Claims 14-18, 21-25, 27, 28, 33-37, 39, and 40 were rejected as being unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,053,033 to Clarke (hereinafter "Clarke") in combination with U.S. Patent No. 5,405,369 to Selman et al. (hereinafter "Selman");
- 2) Claims 14, 19, and 37-39 were rejected as being unpatentable under 35 U.S.C. § 103(a) over Clarke in combination with U.S. Patent No. 5,814,041 to Anderson et al. (hereinafter "Anderson");
- 3) Claims 14-18, 20-25, 27-29, 33-37, 39, and 40 were rejected as being unpatentable under 35 U.S.C. § 103(a) over Clarke in combination with Selman, and further in view of U.S. Patent No. 5,899,882 to Waksman et al. (hereinafter "Waksman"); and
- 4) Claims 25-32 were rejected as being unpatentable under 35 U.S.C. § 103(a) over Clarke in combination with Selman and Waksman, and further in view of U.S. Patent No. 4,799,479 to Spears (hereinafter "Spears").

Appellant filed a Notice of Appeal dated July 16, 2003, regarding rejected Claims 14-40, followed by an Appeal Brief dated October 16, 2003. In response to a Notification of Non-Compliant Brief mailed January 6, 2004, Appellant filed a corrected Appeal Brief on January 29, 2004.

In view of the corrected Appeal Brief filed on January 29, 2004, prosecution was reopened in a Post-Appeal Communication dated May 21, 2004 (hereinafter "the Post-Appeal Communication"). In the Post-Appeal Communication, Claims 14-40 were generally rejected to in the Office Action Summary. Claims 14-25 and 27-40 were substantively rejected in the Post-Appeal Communication on pages 2-5 as follows:

- 1) Claims 14-18, 21, 22, 25, 27, 28, 39, and 40 were rejected as unpatentable under 35 U.S.C. § 103(a) over Selman in combination with Clarke;
- 2) Claims 14, 19, and 37-39 were rejected as being unpatentable under 35 U.S.C. § 103(a) over Anderson et al. in combination with Clarke;
- 3) Claims 20, 23, and 24 were rejected as being unpatentable under 35 U.S.C. § 103(a) over Selman in combination with Clarke, and further in view of Waksman;
- 4) Claims 25, 29, and 30 were rejected as being unpatentable under 35 U.S.C. § 103(a) over Selman in combination with Clarke, and further in view of Waksman and Spears;
- 5) Claims 31 and 32 were rejected as being unpatentable under 35 U.S.C. § 103(a) over Anderson in combination with Clarke, and further in view of U.S. Patent No. 5,617,163 to Ohtake (hereinafter "Ohtake");
- 6) Claims 33 and 34 were rejected as being unpatentable under 35 U.S.C. § 103(a) over Selman in combination with Clarke, and further in view of U.S. Patent No. 4,662,733 to Feinbloom (hereinafter "Feinbloom"); and

- 7) Claims 35 and 36 were rejected as being unpatentable under 35 U.S.C. § 103(a) over Selman in combination with Clarke and Feinbloom, and further in view of U.S. Patent No. 3,970,394 to Stanton (hereinafter "Stanton").

Accordingly, the current status of Claims 14-40 is that each of the claims is rejected, Claims 14-25 and 27-40 being substantively rejected and Claim 26 being generally rejected. Through the Request of Reinstatement of the Appeal and this Substitute Appeal Brief, Appellant seeks reversal of the rejection of Claims 14-40 set forth in the Post Appeal Communication. The claims on appeal are set forth under the heading "VIII. Claims Appendix."

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IV. STATUS OF AMENDMENTS

No amendments were filed subsequent to either the final Office Action or the Post-Appeal Communication.

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V. SUMMARY OF CLAIMED SUBJECT MATTER

As defined by the claims on appeal, Appellant's invention relates to a method for ablating mucosal or endothelial lining, as set for in independent Claim 14. The method of Claim 14 includes steps of providing a light device that includes a flash lamp (7), and inserting the light device inside a patient's body near a mucosal or endothelial lining that is on top of a muscle layer. *See, e.g.*, Application, pg. 3, lines 2-6; and FIG. 1. The method of claim 14 further includes steps of energizing the flash lamp (7) to generate a high intensity ultraviolet light and ablating the mucosal or endothelial lining with the generated light while avoiding causing substantial damage to the muscle layer underneath. *See id.* at pg. 6, lines 24-28.

In one embodiment as defined by Claim 31, the inventive method further includes a step of disposing a lens with a lenticular pattern in a pathway of the light generated by the flash lamp. *See id.* at pg. 6, lines 18-20. The lenticular pattern alters light distribution in a specific manner. In another embodiment as defined by Claim 33, the inventive method further includes a step of stepping up the voltage of the flash lamp's power supply. *See id.* at pg. 6, lines 24-28. This step requires, in addition to the limitations recited by Claim 14, new structural requirements, such as a transformer, besides the flash lamp. *See id.* at pg. 6, line 24, to pg. 7, line 20. Such structural requirements add further strain to the limited space available for intracorporeal operation and present new challenges to the inventor. The additional step also brings additional, non-obvious advantages to the invention, such as making it easier to produce light only of short duration. *See id.* at pg. 7, lines 1-4.

VI. GROUND'S OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 14-18, 21, 22, 25, 27, 28, 39, and 40 are rejected as unpatentable under 35 U.S.C. § 103(a) over Selman in combination with Clarke.

2. Claims 14, 19, and 37-39 are rejected as being unpatentable under 35 U.S.C. § 103(a) over Anderson et al. in combination with Clarke.

3. Claims 20, 23, and 24 are rejected as being unpatentable under 35 U.S.C. § 103(a) over Selman in combination with Clarke, and further in view of Waksman.

4. Claims 25, 29, and 30 are rejected as being unpatentable under 35 U.S.C. § 103(a) over Selman in combination with Clarke, and further in view of Waksman and Spears.

5. Claims 31 and 32 are rejected as being unpatentable under 35 U.S.C. § 103(a) over Anderson in combination with Clarke, and further in view of U.S. Patent No. 5,617,163 to Ohtake (hereinafter referred to as "Ohtake").

6. Claims 33 and 34 are rejected as being unpatentable under 35 U.S.C. § 103(a) over Selman in combination with Clarke, and further in view of U.S. Patent No. 4,662,733 to Feinbloom (hereinafter referred to as "Feinbloom").

7. Claims 35 and 36 are rejected as being unpatentable under 35 U.S.C. § 103(a) over Selman in combination with Clarke and Feinbloom, and further in view of U.S. Patent No. 3,970,394 to Stanton (hereinafter referred to as "Stanton").

Although Appellant believes that the above-identified grounds of rejection correspond to all of the pending rejections, Appellant also appeals any other bases for rejection of the pending claims which were not explicitly stated in the Post-Appeal Communication but which may be regarded as still pending.

VII. ARGUMENT

As discussed below in more detail, the Examiner has failed to establish a *prima facie* case of obviousness of the subject matter of pending Claims 14-40. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). M.P.E.P. 706.02(j).

The initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 U.S.P.Q. 972, 978 (B.P.A.I. 1985). M.P.E.P. 706.02(j).

1. Rejections Under 35 U.S.C. § 103(a) Over Selman in Combination With Clarke

A. Claims 14-18, 21, 22, 25, 27, 28, 39, and 40

Appellant respectfully requests the reversal of the rejections, under 35 U.S.C. § 103(a), of Claims 14-18, 21, 22, 25, 27, 28, 39, and 40. As will be apparent from the arguments presented below, the combination of references cited by the Examiner fails to establish a *prima facie* case of obviousness with respect to these rejected claims.

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The sole independent claim on appeal, Claim 14, recites a method for ablating mucosal or endothelial lining comprising the following steps:

- a) providing a light device comprising a flash lamp;
- b) inserting the light device inside a body near a mucosal or endothelial lining to be ablated, the mucosal or endothelial lining being on top of a muscle layer;
- c) energizing the flash lamp to generate a high intensity ultraviolet light; and
- d) ablating the mucosal or endothelial lining with the generated light, and avoiding causing substantial damage to the muscle layer underneath.

For reasons set forth more fully below, Appellant respectfully submits that (1) Selman and Clarke both teach away from their combination or modification in relation to the claims on appeal; (2) even if the two references are combined, they cannot be reasonably considered to teach or suggest step (d) of instant Claim 14.

1. Selman and Clarke Both Teach Away From Combination or Modification

Selman describes photodynamic treatment of transplanted gastro-intestinal tissue to strip the transplanted tissue of mucus-producing functions (Col. 1, lines 54-68). Specifically, after the mucosal layer of the transplanted tissue takes up photosensitive compositions, the mucosal layer is destroyed when the photosensitive compositions absorb radiation energy (Col. 3, lines 44-52); Col. 6, lines 19-26). As the Examiner recognizes, Selman does not teach the use of a flash lamp as recited in the instant Claim 14 (the Post-Appeal Communication, p. 2, last paragraph).

Clarke is concerned with preventing restenosis after angioplasty (Col. 1, lines 6-10). Clarke's methods are based on the belief that killing smooth muscle cells at an angioplasty site reduces the risk of restenosis (Col. 2, lines 39-50). Accordingly, Clarke's various embodiments are designed to substantially reduce the amount of smooth muscle cells at the angioplasty site

"while minimizing damage to surrounding tissue" (Col. 2, lines 47-50; *see* Col. 5, lines 6-9 and lines 52-62). In contrast to the method recited in the instant Claim 14, methods described in Clarke do not "damag[e] either the inner endothelium layer 22 or the outer adventitia 26 of the blood vessel" (Col. 5, lines 1-5) (emphasis added). Clarke also shows, through FIGS. 3A-3C and 6A-6C, a marked reduction in the thickness of the muscle layer (24) while the endothelial layer (22) retains the same thickness or grows thicker (Col. 5, lines 1-9 and 41-62). Therefore, contrary to step (d) recited in the instant Claim 14, Clarke's methods neither ablate the mucosal or endothelial lining, nor avoid substantial damage to the muscle layer underneath. In fact, as explained above, just the opposite is the case: whereas instant Claim 14 calls for ablation, Clarke's technique aims for preservation.

The teachings of Selman and Clarke cannot reasonably be combined so as to anticipate instant Claim 14. First of all, Selman is concerned with photodynamic treatment, which relies on tissue's absorption of the requisite photosensitive compositions administered to the patient in order to be effective. Clarke, in contrast, directly radiates tissue without the aid of any drug or reagent. The two are dissimilar approaches among medical treatments using photo-radiation. One skilled in the art would not automatically associate the two as interchangeable techniques or look in one approach for modification in the other. More importantly, it is settled that "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959); M.P.E.P. 2143.01. The combination of Selman and Clarke as suggested by the Examiner certainly alters the principle of operation in both references.

Second, both references are very specific in teaching which layer needs to be destroyed to achieve their respective purposes, and the two references target layers that are mutually

exclusive. In Selman, the mucosal layer is destroyed while the muscle layer is saved (Col. 3, lines 44-52). Conversely in Clarke, it is the smooth muscle layer that is destroyed while the mucosal layer is saved (Col. 5, lines 1-5). Therefore, one skilled in the art, knowing that effective thermal absorption by a specific tissue layer requires light of a specific wavelength (and, hence, specific light devices), and knowing that Clarke uses UV radiation to preserve exactly the layer that Selman destroys (Clarke, Col. 5, lines 1-5), would not utilize Clarke's flash lamp for Selman's purpose.

Accordingly, both Selman and Clarke individually teach away from the invention recited in Claim 14 and collectively teach away from their combination. Their teachings are antithetical.

2. Selman and Clarke, Even If Combined, Do Not Teach or Suggest Instant Claim 14

Even if Selman and Clarke are combined, their teachings still fail to teach or suggest all the limitations recited in the instant Claim 14.

Selman's method is able to ablate the mucosal layer while preserving the muscle layer because the two layers absorb different amounts of a photosensitive composition:

The electromagnetic radiation is absorbed by the photosensitive composition and causes a series of chemical reactions which leads to damage or destruction of the mucosal layer of tissue of the transplant bowel segment, while sparing the submucosal and muscular layers of the transplant tissue. The structures of the recipient organ (i.e. the walls, blood vessels and muscle layers) are not damaged because the photosensitive composition does not accumulate in these structures in sufficient amounts to cause damage.

Col. 3, lines 46-59; *see also*, Col. 8, lines 28-31. Selman's written description refers to ultraviolet light only once and in a sweeping statement that lists all portions of electromagnetic radiation as "useful" for its method (Col. 6, lines 35-41). However, immediately following that statement, Selman states that "such luminescence is dependent upon the photosensitive composition being used and the method of treatment" (Col. 6, lines 41-43).

Clarke describes the use of a flash lamp, but uses it to destroy the muscle layer that instant Claim 14 expressly recites to preserve. In other words, to the extent Clarke teaches any utility of a flash lamp, the relevance of Clarke is constrained by its teaching of using UV radiation generated by the flash lamp to *destroy* the muscle layer. Further, Clarke teaches ineffectiveness of UV radiation against the endothelium layer (Col. 5, lines 1-5), the target of instant Claim 14.

Since Selman is silent on any teaching of UV radiation outside the realm of photodynamic treatment, and Clarke teaches that UV radiation is ineffective against the endothelial lining but effective on smooth muscle cells, a hypothetical combination of Selman and Clarke would fail to provide an enabling description of the method recited by instant Claim 14, which recites using high intensity UV radiation generated by a flash lamp to ablate the mucosal or the endothelial lining, while avoiding substantial damage to the muscle layer. The Examiner's assertion that Clarke teaches a flash lamp to be the equivalent to laser does not dispose of the issue. Clarke, at best, suggests that a UV flash lamp may be used as an alternative to a laser apparatus as the source of UV radiation (Col. 2, lines 51-62), but is silent on UV radiation's effect on photosensitive compositions foreign to the body.

At least for reasons stated in Sections 1(A)(1) and 1(A)(2), Appellant asserts that instant Claim 14 and its dependent claims including Claims 15-18, 21, 22, 25, 27, 28, 39, and 40 are non-obvious over Selman and Clarke, and respectfully requests the reversal of the rejections under 35 U.S.C. § 103(a).

2. Rejections Under 35 U.S.C. § 103(a) Over Anderson in Combination With Clarke

A. Claims 14, 19, and 37-39

Anderson describes a method for producing a uniform pattern of illumination in laser-based photodynamic therapy in order to ablate the endometrium, i.e., the mucous membrane

lining the uterus (Col. 1, lines 24-52; Col. 5, lines 10-47). As the Examiner recognizes, Anderson does not teach the use of a flash lamp, an element recited in the instant Claim 14 (the Post-Appeal Communication, p. 5, first paragraph). Moreover, like Selman, Anderson describes a method that targets a tissue layer excluded by Clarke, namely, the mucous membrane. Accordingly, the skilled artisan would also be dissuaded from combining the disclosure of Anderson and Clarke as the two references target mutually exclusive tissue layers.

Similar to Selman, Anderson's teaching is limited to improvement in photodynamic treatment. Specifically, Anderson teaches that the endometrium responds to Photofrin treatment better than surrounding tissue including the myometrium, which is the smooth muscle of uterus (Col. 1, lines 46-52). Contrary to the Examiner's assertion (the Post-Appeal Communication, p. 3, first paragraph), Anderson does not teach that the endometrium responds to light ablation. Anderson teaches that the endometrium can be ablated if treated with a photosensitive composition that renders it vulnerable to ablation (*see* Col. 15, lines 16-35). In other words, Anderson implies that under natural conditions, the endometrium is not responsive to light ablation, which is consistent with Clarke's description that UV radiation is ineffective against endothelial lining. Therefore, even if combined, Anderson and Clarke would fail to anticipate instant Claim 14 at least because they do not teach or suggest the ablating of the mucosal or endothelial lining with UV radiation while avoiding substantial damage to the muscle layer underneath.

At least for reasons stated above, Appellant submits that instant Claim 14 and its dependent claims 19 and 37-39 are non-obvious over Anderson and Clarke, and respectfully requests reversal of the rejections under 35 U.S.C. § 103(a).

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3. Rejections Under 35 U.S.C. § 103(a) Over Selman in Combination With Clarke and Waksman

A. Claims 20, 23, and 24

Waksman describes using a radioactive material to inhibit formation of scar tissue following balloon angioplasty (Abstract; Col. 2, lines 14-67). Waksman does not provide any teaching that remedies the deficiency of Selman and Clarke with respect to instant Claim 14, as discussed above in Section 1.

Waksman does not concern use of photosensitive materials (Selman) or use of light (Clarke). Instead, Waksman describes using radioactive materials as the energy source (Col. 7, lines 14-19 and 41-48). Accordingly, Waksman does not provide any suggestion as to why and how Selman and Clarke's teachings can be combined or modified to provide a step of ablating the mucosal or endothelial lining using UV light generated by a flash lamp while avoiding substantial damage to the muscle layer, as required by instant Claim 14.

At least for reasons stated above, Appellant submits that instant Claims 20, 23, and 24, each dependent from Claim 14, are non-obvious over Selman and Clarke, and further in view of Waksman, and respectfully requests reversal of the rejections under 35 U.S.C. § 103(a).

4. Rejections Under 35 U.S.C. § 103(a) Over Selman in Combination With Clarke, Waksman, and Spears

A. Claims 25, 29, and 30

Spears describes heating an expanded intraluminal balloon to fuse together segments of tissue fragmented during balloon angioplasty in order to prevent restenosis (Abstract). Spears does not provide any teaching that remedies the deficiency of Selman, Clarke, and Waksman with respect to instant Claim 14, as discussed above in Sections 1 and 3.

First, Spears describes using laser output through optical fibers (Col. 3, lines 32-45; Col. 5, lines 43-62) or an electrical heating element (Col. 9, lines 37-43) to provide heat. Spears is silent with respect to ultraviolet light or flash lamp. Second, similar to Clarke, Spears teaches

that "thermal destruction of the smooth muscle cell provided by the subject technique prevents [hyperplasia] response," (Col. 2, lines 53-59, teaching away from saving the muscle layer, as recited in instant Claim 14.) Accordingly, Spears does not provide any suggestion as to why and how Selman, Clarke, and Waksman's teachings can be combined or modified to provide a step of ablating the mucosal or endothelial lining using UV light generated by a flash lamp while avoiding substantial damage to the muscle layer, as required by instant Claim 14.

At least for reasons stated above, Appellant submits that instant Claims 25, 29, and 30, each dependent from Claim 14, are non-obvious over Selman, Clarke, and further in view of Waksman and Spears, and respectfully requests reversal of the rejections under 35 U.S.C. § 103(a).

5. Rejections Under 35 U.S.C. § 103(a) Over Anderson in Combination With Clarke and Ohtake

A. Claims 31 and 32

Ohtake describes a camera including a Fresnel lens (Abstract). Ohtake does not teach or suggest medical use of light, therefore, does not suggest why one should combine aspects of Clarke's UV therapy with Anderson's photodynamic treatment. Accordingly, Ohtake does not provide any suggestion as to why and how Anderson and Clarke's teachings can be combined or modified to provide a step of ablating the mucosal or endothelial lining using UV light generated by a flash lamp while avoiding substantial damage to the muscle layer, as required by instant Claim 14.

Moreover, Ohtake is silent as to why Fresnel lens should be used in an *in vivo* tissue ablation method. Accordingly, Ohtake does not provide any reason to combine its teaching with the teachings of Anderson and Clarke.

At least for reasons stated above, Appellant submits that instant Claims 31 and 32, each dependent from Claim 14, are non-obvious over Anderson in combination with Clarke, and

further in view of Ohtake, and respectfully requests reversal of the rejections under 35 U.S.C. § 103(a).

6. Rejections Under 35 U.S.C. § 103 Over Selman in Combination With Clarke and Feinbloom

A. Claims 33 and 34

Feinbloom describes using a condensing lens to focus light from a flash bulb for capturing the color red better on slow-speed films. Feinbloom does not concern medical treatment, either in photodynamic treatment or spectroscopy. Therefore, Feinbloom does not provide any suggestion as to why and how Selman and Clarke's teachings can be combined or modified to provide the steps recited in instant Claim 14.

Moreover, Feinbloom is silent as to why the power supply's voltage should be stepped up in an *in vivo* tissue ablation method. Accordingly, Feinbloom does not provide any reason to combine its teaching with the teachings of Selman and Clarke with regard to instant Claim 33.

At least for reasons stated above, Appellant submits that instant Claims 33 and 34, each dependent from Claim 14, are non-obvious over Selman in combination with Clarke, and further in view of Feinbloom, and respectfully requests reversal of the rejections under 35 U.S.C. § 103(a).

7. Rejections Under 35 U.S.C. § 103 Over Selman in Combination With Clarke, Feinbloom, and Stanton

A. Claims 35 and 36

Stanton describes using fiber optics to transmit sensed light signals to sensors in a densitometer, enabling the device to be mounted in small spaces (Summary). Stanton does not concern medical treatment, either in photodynamic treatment or spectroscopy. Neither does Stanton provide reasons why the power supply's voltage should be stepped up in an *in vivo* tissue ablation method. Therefore, Stanton does not provide any suggestion as to why and how the

teachings of Selman, Clarke, and Feinbloom can be combined or modified to provide the steps recited in instant Claim 33.

At least for reasons stated above, Appellant submits that instant Claims 35 and 36, each depending from instant Claim 33, which in turn, depends from Claim 14, are non-obvious over Selman in combination with Clarke and Feinbloom, and further in view of Stanton, and respectfully requests the reversal of the rejections under 35 U.S.C. § 103(a).

8. Claimed Invention is Patentable Under Any Other Possible Bases for Rejection

Appellant believes that the foregoing arguments address each of the pending rejections of the pending claims. In particular, the instant Substitute Appeal Brief addresses each of the rejections made in the Post-Appeal Communication. Accordingly, Appellant submits that the instant application meets all requirements for patentability.

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VIII. CONCLUSION

For the reasons given above, it is respectfully requested that the rejections in the Post-Appeal Communication be reversed and the application be passed to issue with Claims 14-40 as presented in the Claims Appendix.

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IX. CLAIMS APPENDIX

14. A method for ablating mucosal or endothelial lining, comprising:

- a) providing a light device comprising a flash lamp;
- b) inserting the light device inside a body near a mucosal or endothelial lining to be ablated, the mucosal or endothelial lining being on top of a muscle layer;
- c) energizing the flash lamp to generate a high intensity ultraviolet light; and
- d) ablating the mucosal or endothelial lining with the generated light, and avoiding causing substantial damage to the muscle layer underneath.

15. The method of claim 14 wherein the mucosal lining comprises a mucosal lining of an esophagus.

16. The method of claim 14 wherein the mucosal lining comprises a mucosal lining of a throat.

17. The method of claim 14 wherein the mucosal lining comprises a mucosal lining of an intestine.

18. The method of claim 14 wherein the mucosal lining comprises a mucosal lining of a colon.

19. The method of claim 14 wherein the endothelial lining comprises an endothelial lining of a uterus.

20. The method of claim 14 wherein the endothelial lining comprises an endothelial lining of a urethra.

21. The method of claim 14 wherein the endothelial lining comprises an endothelial lining of a bladder.

22. The method of claim 14 wherein the endothelial lining comprises an endothelial lining of an organ.

23. The method of claim 14 wherein the endothelial lining comprises an endothelial lining of a duct.

24. The method of claim 14 wherein the endothelial lining comprises an endothelial lining of a vessel.

25. The method of claim 14 further comprising disposing the light device at a distal end of an interventional device and inserting the interventional device inside the body near the mucosal or endothelial lining to be ablated.

26. The method of claim 25 further comprising transporting a fluid to the light device to dissipate heat generated by the light device.

27. The method of claim 14 further comprising characterizing a targeted portion of the mucosal or endothelial lining by transporting a dye to the mucosal or endothelial lining to stain the targeted portion and wherein the step of ablating the mucosal or endothelial lining comprises using light absorbed by the stained portion.

28. The method of claim 14 further comprising introducing a drug near the mucosal or endothelial lining and activating the drug through the light.

29. The method of claim 25 wherein the interventional device comprises an expandable balloon enclosing the light device.

30. The method of claim 29, further comprising transporting a fluid to the balloon to dissipate heat generated by the light device.

31. The method of claim 14, further comprising disposing a lens comprising a lenticular pattern in a pathway of the light generated by the flash lamp.

32. The method of claim 31 wherein the lenticular pattern comprises a fresnel pattern.

33. The method of claim 14, further comprising stepping up the voltage of a power supplied to the flash lamp.

34. The method of claim 33 wherein stepping up the voltage comprises connecting the flash lamp to a transformer.

35. The method of claim 33 wherein stepping up the voltage comprises using a separate lead connected to a foil disposed adjacent the flash lamp.

36. The method of claim 33 wherein stepping up the voltage comprises depositing a layer of metalization adjacent the flash lamp.

37. The method of claim 14 further comprising redirecting some of the light generated by the flash lamp.

38. The method of claim 37 wherein redirecting some of the light comprises using a reflector.

39. The method of claim 14 further comprising filtering the light generated by the flash lamp.

40. The method of claim 27 wherein the targeted portion of the mucosal or endothelial lining comprises a diseased portion.

X. EVIDENCE APPENDIX

None.

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XI. RELATED PROCEEDINGS APPENDIX

None.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service in a sealed envelope as first-class mail with postage thereon fully prepaid and addressed to Mail Stop Appeal Brief--Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the below date.

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